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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/701,278	08/22/95	ANDERSON	A-63770-1/RF

HM22/0503
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EXAMINER

HAYES, R

ART UNIT

1644

PAPER NUMBER

26

DATE MAILED:

05/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
08/701,278

Applicant(s)

Anderson et al

Examiner

Robert C. Hayes

Group Art Unit

1644



☒ Responsive to communication(s) filed on Feb 18, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 2, and 4-7 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, and 4-7 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1644

DETAILED ACTION

Response to Amendment

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1644.
2. The amendment filed 2/18/00 has been entered.
3. The Declarations of Qi Sun and Amy Greenwood under 37 CFR 1.132 filed 2/18/00 are sufficient to overcome the rejection of claims 1-2 & 4-7 under 35 U.S.C. 102(a) as being anticipated by Saito et al., as maintained in the Office action of 4/12/99 (Paper No.17), as well as the rejection under 35 U.S.C. 102(f) because applicants now clearly did invent the claimed subject matter.
4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 & 4-7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility.

Art Unit: 1644

While the specification asserts an utility for the instant invention (e.g., page 20 of the specification) as a “molecular marker to identify neurons in the peripheral sensory lineage”, and that “the pattern of expression of DRG11 in the central nervous system suggests that DRG11 *may function* in regulating some aspect of the connectivity between these neurons and their central targets”, “DRG11 proteins, nucleic acids and antibodies [cannot reasonably be] useful in the screening and diagnosis of the presence or absence of DRG11 in a variety of cell types”, because no known biological activity is known or described within the specification that is associated with even the preferred nucleic acid embodiment depicted as SEQ ID NO:1. Nor is any specific sensory neuronal disease state known or disclosed for carrying out such “screening and diagnosis”. Therefore, no “specific utility” exists for the claimed polynucleotides at the time of filing the instant specification, because many genes are expressed in a particular cell type; thereby, not being “specific”, by definition, because such “markers” apply to a *general* class of compounds. In addition, the claimed polynucleotides have no “substantial utility” because further experimentation is necessary at the time of filing the instant invention to attribute a “real world” utility to the claimed polynucleotides. The rationale is that one would expect that a limited number of dysfunctional genes would be useful as markers for diseases, versus the generalized “molecular marker to identify neurons in the peripheral sensory lineage” asserted for the single disclosed DRG11 gene.

Applicant is directed toward the Revised Interim Utility Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999.

Art Unit: 1644

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 & 4-7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. Claims 1-2 & 4-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No written description is provided in the instant specification as to what structurally constitutes nucleotide sequences comprising unknown and undescribed promoter sequences, 5'- or 3'-flanking or enhancer regions, introns, allelic variants, or other sequences comprising any DRG11 encoding sequence, in that no sequences for these different molecules are described; nor can they be visualized by one skilled in the art. It is suggested that amending all claims to “an isolated cDNA [nucleic acid] encoding...” should obviate this particular rejection.

Art Unit: 1644


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
May 2, 2000



CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800 1644